AD-A129 769 TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT REPELLENT AI3-70307GD(U) ARMY ENVIRONMENTAL HYGIENE AGENCY ABERDEEN PROVING GROUND MD J V WADE APR 83 1/1

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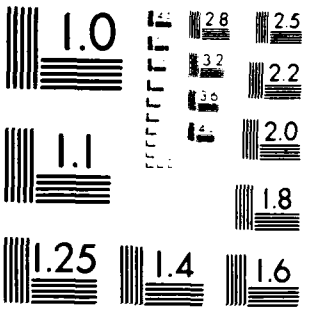

UNITED STATES ARMY ENVIRONMENTAL HYGIENE AGENCY

ABERDEEN PROVING GROUND, MD 21010

TOPICAL HAZARD EVALUATION PROGRAM
OF
CANDIDATE INSECT REPELLENT AI3-70307Gd
US DEPARTMENT OF AGRICULTURE PROPRIETARY CHEMICAL
STUDY NO. 75-51-0428-83
MARCH - APRIL 1983

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Skin Irritation
Topical Hazard Evaluation Program
USDA Proprietary Chemicals

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

Preliminary hazard evaluation of AI3-70307Gd was performed by means of laboratory studies. The chemical produced severe primary irritation of the intact skin and of the skin surrounding an abrasion. It additionally produced eschars in all animals tested between the 3rd and 7th day postapplication.

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DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010

CPT Wade/cw/AUTOVON
584-3980

REPLY TO ATTENTION OF
HSHB-OT/WP

8 JUN 1983

SUBJECT: Topical Hazard Evaluation Program of Candidate Insect Repellent AI3-70307Gd, US Department of Agriculture Proprietary Chemical, Study Number 75-51-0428-83, March - April 1983

Executive Secretary
Armed Forces Pest Management Board
Forest Glen Section, WRAMC
Washington, DC 20307

EXECUTIVE SUMMARY

The purpose, essential findings and recommendations of the inclosed report follow:

a. Purpose. The purpose of this program is to provide guidance for further Entomological Testing of the Candidate Insect Repellent AI3-70307Gd by means of laboratory animal studies using New Zealand White rabbits.

b. Essential Findings. Chemical AI3-70307Gd produced severe primary irritation of the intact skin and the skin surrounding an abrasion in New Zealand White rabbits. It additionally produced eschars in all animals tested between the 3d and 7th days postapplication.

c. Major Recommendation. Disapprove Chemical AI3-70307Gd for further testing. If repellent properties warrant, it should be purified and resubmitted for testing in the form and at the concentration intended for use.

FOR THE COMMANDER:

JOHN W. CUTTING, M.D.
Colonel, MC
Director, Occupational and Environmental Health

1 Incl
as (5 cy)

CF:
HQDA (DASG-PSP) wo incl
Cdr, HSC (HSPA-P)
Dir, Advisory Cen on TOX, NRC
Comdt, AHS (HSHA-IPM)
USDA, ARS (Dr. Terrence McGovern)
USDA, ARS-Southern Region (3 cy)
USDA, ARS-Southern Region (LTC Reinert)

DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010

REPLY TO ATTENTION OF
HSHB-OT/WP

TOPICAL HAZARD EVALUATION PROGRAM OF CANDIDATE INSECT REPELLENT AI3-70307Gd US DEPARTMENT OF AGRICULTURE PROPRIETARY CHEMICAL STUDY NO. 75-51-0428-83 MARCH - APRIL 1983

1. AUTHORITY.

a. Letter, US Department of Agriculture, Agricultural Research Service, Southern Region, Gainesville, Florida, 10 March 1983.

b. Memorandum of Understanding between the US Army Environmental Hygiene Agency; the US Army Health Services Command; The Department of the Army, Office of The Surgeon General; The Armed Forces Pest Control Board; and the Department of Agriculture, Agricultural Research, Science and Education Administrations; titled Coordination of Biological and Toxicological Testing of Pesticides, effective 23 January 1979.

2. REFERENCE. US Army Environmental Hygiene Agency, Toxicology Division, Topical Hazard Evaluation Program Procedural Guide, January 1982.

3. PURPOSE. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellent AI3-70307Gd, US Department of Agriculture (USDA) Proprietary Chemical.

4. SUMMARY OF FINDINGS. Hazard evaluation of the candidate repellent AI3-70307Gd, USDA Proprietary Chemical, was conducted by this Agency using New Zealand White rabbits for primary skin irritation studies. A tabular presentation of animal toxicity data developed by this Agency follows:*†

TABLE. PRESENTATION OF DATA

Test	Results	Interpretation
SKIN IRRITATION STUDIES		
Rabbits		
Single 24-hour application to intact and abraded skin of New Zealand White rabbits. 0.5 ml of technical grade chemical applied to each of six rabbits (repeated with six additional rabbits).	Chemical AI3-70307Gd produced severe primary irritation of the intact skin and the skin surrounding an abrasion, and additionally produced eschars in all animals tested between the 3d and 7th day postapplication.	USAEHA Category IV (ref Appendix A)

* In conducting the studies described in this report, the investigators adhered to the "Guide for the Care and Use of Laboratory Animals," US Department of Health, Education, and Welfare Publication No. (NIH) 80-23, revised 1978.
† The studies reported herein were performed in animal facilities fully accredited by the American Association for the Accreditation of Laboratory Animal Care.

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5. CONCLUSION. Chemical AI3-70307Gd produced severe primary irritation of the intact skin and the skin surrounding an abrasion, and additionally produced eschars in all animals tested between the 3d and 7th days postapplication. These studies were monitored by Analytical Quality Assurance Office (See Appendix B).

6. RECOMMENDATION. Disapprove USDA Proprietary Chemical AI3-70307Gd for further testing (under the provisions of the Memorandum of Understanding, paragraph 1b, this report). If repellent properties warrant, chemical should be purified and resubmitted for testing in the form and at the concentration intended for use.

JOHN V. WADE, DVM
CPT, VC
Laboratory Animal Veterinary Officer
Toxicology Division

APPROVED:

TIMOTHY B. WEYANDT, M.D., M.P.H
MAJ, MC
Acting Chief, Toxicology Division

APPENDIX A

TOPICAL HAZARD EVALUATION PROGRAM
DEFINITIONS OF CATEGORIES OF COMPOUNDS BEING
CONSIDERED FOR ACUTE SKIN APPLICATION

CATEGORY I - Compounds producing no primary irritation of the intact skin or no greater than mild primary irritation of the skin surrounding an abrasion. (INTERPRETATION: No restriction for acute application to the human skin.)

CATEGORY II - Compounds producing mild primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should be used only on human skin found by examination to have no abrasions or may be used as a clothing impregnant.)

CATEGORY III - Compounds producing moderate primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should not be used directly on the skin without a prophetic patch test having been conducted on humans to determine irritation potential to human skin. May be used without patch testing, with extreme caution, as clothing impregnants. Compound should be resubmitted in the form and at the intended use concentration so that its irritation potential can be reexamined using other test techniques on animals.)

CATEGORY IV - Compounds producing moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, producing necrosis, vesiculation, and/or eschars. (INTERPRETATION: Should be resubmitted for testing in the form and at the intended use concentration. Upon resubmission, its irritation potential will be reexamined using other test techniques on animals, prior to possible prophetic patch testing in humans, at concentrations which have been shown not to produce primary irritation in animals.)

CATEGORY V - Compounds impossible to classify because of staining of the skin or other masking effects owing to physical properties of the compound. (INTERPRETATION: Not suitable for use on humans.)

EYE CATEGORIES:

A. Compounds noninjurious to the eye. INTERPRETATION: Irritation of human eyes is not expected if the compound should accidentally get into the eyes, provided it is washed out as soon as possible.

B. Compounds producing mild injury to the cornea. INTERPRETATION: Should be used with caution around the eyes.

C. Compounds producing mild injury to the cornea, and in addition some injury to the conjunctiva. INTERPRETATION: Should be used with caution around the eyes and mucosa.

D. Compounds producing moderate injury to the cornea. INTERPRETATION: Should be used with extreme caution around the eyes.

E. Compounds producing moderate injury to the cornea, and in addition producing some injury to the conjunctiva. INTERPRETATION: Should be used with extreme caution around the eyes and mucosa.

F. Compounds producing severe injury to the cornea and to the conjunctiva. INTERPRETATION: Should be used with extreme caution. It is recommended that use be restricted to areas other than the face.

APPENDIX B

ANALYTICAL QUALITY ASSURANCE

The Analytical Quality Assurance Office certifies the following with regard to this study:

a. This study was conducted in accordance with:

(1) Standing Operating Procedures developed by the Toxicology Division, USAEHA.

(2) Title 21, Code of Federal Regulations, 1981 rev, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

b. Facilities were inspected during its operational phase to insure compliance with paragraph a above.

c. The information presented in this report accurately reflects the raw data generated during the course of conducting the study.

PAUL V. SNEERINGER, Ph.D.
Chief, Analytical Quality
Assurance Office


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